HFA - 305

Date Approval: JUN 18 2002

FREEDOM OF INFORMATION SUMMARY

Original Abbreviated New Animal Drug Application

Oxytetracycline injection (200 mg/mL)

ANADA 200-306

Sponsored by:

Norbrook Laboratories, Ltd.
105 Armagh Road
Newry BT35 6PU
Northern Ireland

ANADA 200-306 FOIS

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	ANADA 200-306
Sponsor Name:	Norbrook Laboratories, Ltd. Northern Ireland
Established Name:	Oxytetracycline injection
Trade/Proprietary Name:	Oxytetracycline Injection 200 mg/mL
Dosage Form:	Sterile injectable solution
How Supplied:	100, 250 & 500 mL bottles
How Dispensed:	OTC
Amount of Active Ingredient:	200 mg of oxytetracycline per mL
Route of Administration:	Intramuscular in swine; intramuscular, subcutaneously, and intravenous in cattle
Species:	Beef cattle, dairy cattle, calves, including preruminating (veal) calves and swine
Pioneer Product/"Listed" Product:	Liquamycin® LA-200®, oxytetracycline injection; NADA 113-232; Pfizer, Inc.

2. INDICATION FOR USE:

Oxytetracycline Injection (200 mg/mL) is intended for use in the treatment of the following diseases in beef cattle, dairy cattle, calves, including preruminating (veal) calves and swine when due to oxytetracycline susceptible organisms.

CATTLE

Oxytetracycline Injection (200 mg/mL) is indicated in the treatment of the pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine *keratoconjunctivitis* (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresi*; leptospirosis caused by *Leptospira*

pomona; and wound infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

SWINE

In swine, Oxytetracycline Injection (200 mg/mL) is indicated in the treatment of the bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused *by Leptospira pomona.*

In sows, Oxytetracycline Injection (200 mg/mL) is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

3. DOSAGE:

CATTLE

Oxytetracycline Injection (200 mg/mL) is to be administered by intramuscular, intravenous or subcutaneous injection to beef cattle, dairy cattle, and calves, including preruminating (veal) calves.

A single dose of 9 mg of Oxytetracycline Injection (200 mg/mL) per pound of body weight administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

Oxytetracycline Injection (200 mg/mL) is to be administered by intramuscular, intravenous or subcutaneous injection at a level 3 to 5 mg of oxytetracycline per pound of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg per pound of body weight per day is recommended. Treatment should be continued 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

SWINE

A single doses of 9 mg of Oxytetracycline Injection (200 mg/mL) per pound of body weight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Oxytetracycline Injection (200 mg/mL) can also be administered by intramuscular injection at a level of 3 to 5 mg of oxytetracycline per pound of body weight per day. Treatment should be continued 24 to 48 hours following remission of diseases signs; however, not to

exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment

For sows, administer once intramuscularly 3 mg. of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb. of body weight and under, Oxytetracycline Injection (200 mg/mL) should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

4. TARGET ANIMAL SAFETY AND EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADAs for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October, 2000).

Based upon the formulation characteristics of the generic product, Norbrook Laboratories, Ltd., was granted a waiver [dated April 13, 1994] from conducting an *in vivo* bioequivalence study for oxytetracycline injection. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

5. HUMAN FOOD SAFETY:

Tolerance

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows:

(a) 2 parts per million (ppm) in muscle
(b) 6 ppm in liver
(c) 12 ppm in fat and kidney

The ADI for total tetracycline residues is 25 micrograms per kilogram of body weight per day (21CFR 556.500).

Withdrawal time

The withdrawal times are those previously assigned to the pioneer product. The withdrawal time for oxytetracycline injection is established under 21 CFR 522.1660; 28 days for cattle and swine.

Regulatory Method for Residues

The analytical method for detection of residues of the drug is the cylinder plate microbiological test using Bacillus cereus var. mycoides (ATCC 11778) as outlined in the "Antibiotic Residues in Milk, Dairy Product and Animal Tissues: Methods, Reports, and Protocols" October 1968. National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204. (Copies available from FDA, Center for Veterinary Medicine, 7500 Standish Place, Rockville Maryland 20855).

6. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, And Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Oxytetracycline base (200 mg/mL) when used under the proposed conditions of use, is safe and effective for its labeled indications.

7. LABELING:

Attachments:

The generic Oxytetracycline Injection labeling and approved pioneer Liquamycin® LA-200® labeling.

Generic	Pioneer
100 mL & 250 mL – bottles –	100 mL & 250 mL – bottles –
500 mL – bottle – Oxytetracycline Injection	500 mL – bottle – Liquamycin LA-200
Package insert – Oxytetracycline Injection	Package insert – Liquamycin LA-200
Cartons	Cartons

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

4697

Liquamycin® LA-200®

(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

Net Contents: 500 mL

NADA #113-232, Approved by FDA

0 87219 04697 5

Pfizer

Liquamycin® LA-200®

(oxytetracycline injection)

104984000

986 10-4984-00-0

Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline.

Caution: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

Warnings: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

Precautions: Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

Restricted Drug (California)—
Use Only as Directed

Not for Human Use

TAKE TIME  OBSERVE LABEL DIRECTIONS

Distributed by:
Animal Health
Exton, PA 19341, USA
Div of Pfizer Inc
NY, NY 10017

Liquamycin® LA-200®

(oxytetracycline injection)

Cattle Dosage Guide

At the first signs of pneumonia or pinkeye,* administer a single dose of Liquamycin LA-200 by deep intramuscular injection, or subcutaneously, according to the following weight categories.**

Animal Weight (lb)	Number of mL or cc	Animal Weight (lb)	Number of mL or cc
100	4.5	700	31.5
200	9.0	800	36 0
300	13.5	900	40.5
400	18.0	1000	45.0
500	22.5	1100	49.5
600	27.0	1200	54.0

* See package insert for dosing instructions for other indicated diseases and full product information

** Do not administer more than 10 mL at any one injection site (1–2 mL per site in small calves)

Discontinue treatment at least 28 days prior to slaughter.

Swine Dosage Guide

At the first signs of pneumonia,* administer Liquamycin LA-200 by deep intramuscular injection according to the following weight categories.**

Animal Weight (lb)	Number of mL or cc	Animal Weight (lb)	Number of mL or cc
10	0.5	175	7.9
25	1.1	200	9.0
50	2.3	225	10.1
75	3.4	250	11.3
100	4.5	275	12.4
125	5.6	300	13.5
150	6.8	325	14.6

* See package insert for dosing instructions for other indicated diseases and full product information.

** Do not administer more than 5 mL at any one injection site.

Discontinue treatment at least 28 days prior to slaughter.

986
10-4984-00-0
U.S. Patent No. 4,018,889 Made in USA

Liquamycin® LA-200®

(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For use in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

Read Entire Package Insert Carefully Before Using This Product

Liquamycin LA-200 (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline (Terramycin®) by injection. Terramycin, discovered by Pfizer scientists, is an antimicrobial agent that is effective in the treatment of a wide range of diseases caused by susceptible gram-positive and gram-negative bacteria.

Liquamycin LA-200 administered to cattle or swine for the treatment of bacterial pneumonia at an intramuscular dosage of 9 mg of oxytetracycline per lb of body weight has been demonstrated in clinical trials to be as effective as 2 or 3 repeated, daily treatments of Terramycin Injectable at 3–5 mg/lb of body weight.

Liquamycin LA-200 does not require refrigeration; however, it is recommended that it be stored at room temperature, 15°–30°C (59°–86°F). The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum, or exudates.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

WARNINGS: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

PRECAUTIONS: Exceeding the highest recommended dosage level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Reactions of an allergic or anaphylactic nature, sometimes fatal, have been known to occur in hypersensitive animals following the injection of oxytetracycline. Such adverse reactions can be characterized by signs such as restlessness, erection of hair, muscle trembling; swelling of eyelids, ears, muzzle, anus, and vulva (or scrotum and sheath in males); labored breathing, defecation and urination, glassy-eyed appearance, eruption of skin plaques, frothing from the mouth, and prostration. Pregnant animals that recover may subsequently abort. At the first sign of any adverse reaction, discontinue use of this product and administer epinephrine at the recommended dosage levels. Call a veterinarian immediately.

Shock may be observed following intravenous administration, especially where highly concentrated materials are involved. To minimize this occurrence, it is recommended that Liquamycin LA-200 be administered *slowly* by this route.

Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving Liquamycin LA-200 in conjunction with penicillin.

STORAGE: Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

CARE OF SICK ANIMALS: The use of antibiotics in the management of diseases is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with Liquamycin LA-200 show a noticeable improvement within 24–48 hours. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, costs, and needless losses. Good housing, sanitation, and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased animals.

INDICATIONS: Liquamycin LA-200 is intended for use in the treatment of the following diseases in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine when due to oxytetracycline-susceptible organisms:

Cattle: Liquamycin LA-200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus*

Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving Liquamycin LA-200 in conjunction with penicillin.

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Cattle: Liquamycin LA-200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis;* foot rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresii;* leptospirosis caused by *Leptospira pomona;* and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

Swine: Liquamycin LA-200 is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli;* pneumonia caused by *Pasteurella multocida;* and leptospirosis caused by *Leptospira pomona.*

In sows, Liquamycin LA-200 is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

DOSAGE:

Cattle: Liquamycin LA-200 is to be administered by intramuscular, subcutaneous, or intravenous injection to beef cattle; dairy cattle; and calves, including preruminating (veal) calves.

A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis.*

Liquamycin LA-200 can also be administered by intravenous, subcutaneous, or intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg/lb of body weight per day is recommended. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

Swine: A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Liquamycin LA-200 can also be administered by intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

For sows, administer once intramuscularly 3 mg of oxytetracycline per lb of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb of body weight and under, Liquamycin LA-200 should be administered *undiluted* for treatment at 9 mg/lb but should be administered *diluted* for treatment at 3 or 5 mg/lb.

	9 mg/lb Dosage	3 or 5 mg/lb Dosage		
Body Weight	Volume of Undiluted Liquamycin LA-200 9 mg/lb	Volume of Diluted Liquamycin LA-200 3 mg/lb	Dilution*	5 mg/lb
5 lb	0.2 mL	0.6 mL	1:7	1.0 mL

DIRECTIONS FOR USE: Liquamycin LA-200 is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, Liquamycin LA-200 should be warmed to room temperature before administration to animals. Before withdrawing the solution from the bottle, disinfect the rubber cap on the bottle with suitable disinfectant, such as 70% alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 16–18 gauge and 1–1½ inches long are adequate for intramuscular and subcutaneous injections. Needles 2–3 inches are recommended for intravenous use.

Intramuscular Administration:
Intramuscular injections should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle such as in the rump, hip, or thigh regions; avoid blood vessels and major nerves. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. No more than 10 mL should be injected intramuscularly at any one site in adult beef and dairy cattle, and not more than 5 mL per site in adult swine; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1–2 mL per site is injected in small calves.

Subcutaneous Administration:
Subcutaneous injections in beef cattle, dairy cattle, and calves, including preruminating (veal) calves, should be made by directing the needle of suitable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the tip of the needle has penetrated the skin but is not lodged in muscle. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. The solution should be injected slowly into the area between the skin and muscles. No more than 10 mL should be injected subcutaneously at any one site in adult beef and dairy cattle; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1–2 mL per site is injected in small calves.

Intravenous Administration:
Liquamycin LA-200 may be administered intravenously to beef and dairy cattle. As with all highly concentrated materials, Liquamycin LA-200 should be administered *slowly* by the intravenous route.

Preparation of the Animal for Injection:
1. Approximate location of vein. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the brisket and slightly above and to the side of the windpipe (see Fig. I).
2. Restraint. A stanchion or chute is ideal for restraining the animal. With a halter, rope, or cattle leader (nose tongs), pull the animal's head around the side of the stanchion, cattle chute, or post in such a manner to form a bow in the neck (see Fig. II), then snub the head securely to prevent movement. By forming the bow in the neck, the outside curvature of the bow tends to expose the jugular vein and make it easily accessible. **Caution:** Avoid restraining the animal with a tight rope or halter around the throat or upper neck which might impede blood flow. Animals that are down present no problem so far as restraint is concerned.
3. Clip hair in area where injection is to be made (over the vein in the upper third of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.

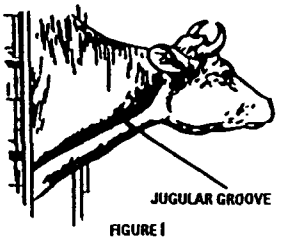

FIGURE I

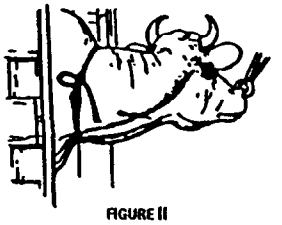
FIGURE II

Entering the Vein and Making the Injection:
1. Raise the vein. This is accomplished by tying the choke rope tightly around the neck close to the shoulder. The rope should be tied in such a way that it will not come loose and so that it can be untied quickly by pulling the loose end (see Fig. II). In thick-necked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back to the heart. Under ordinary conditions it cannot be seen or felt with the fingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands

throat or upper neck which might impede blood
no problem so far as restraint is concerned.
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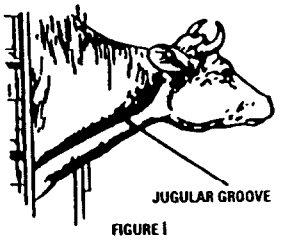

FIGURE I

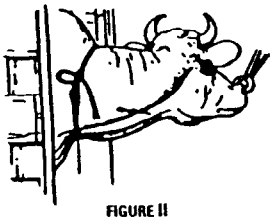
FIGURE II

Entering the Vein and Making the Injection:

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2. Inserting the needle. This involves 3 distinct steps. First, insert the needle through the hide. Second, insert the needle into the vein. This may require 2 or 3 attempts before the vein is entered. The vein has a tendency to roll away from the point of the needle, especially if the needle is not sharp. The vein can be steadied with the thumb and finger of one hand. With the other hand, the needle point is placed directly over the vein, slanting it so that its direction is along the length of the vein, either toward the head or toward the heart. Properly positioned this way, a quick thrust of the needle will be followed by a spurt of blood through the needle, which indicates that the vein has been entered. Third, once in the vein, the needle should be inserted along the length of the vein all the way to the hub, exercising caution to see that the needle does not penetrate the opposite side of the vein. Continuous steady flow of blood through the needle indicates that the needle is still in the vein. If blood does not flow continuously, the needle is out of the vein (or clogged) and another attempt must be made. If difficulty is encountered, it may be advisable to use the vein on the other side of the neck.
3. While the needle is being placed in proper position in the vein, an assistant should get the medication ready so that the injection can be started without delay after the vein has been entered.
4. Making the injection. With the needle in position as indicated by continuous flow of blood, release the choke rope by a quick pull on the free end. This is essential—the medication cannot flow into the vein while it is blocked. Immediately connect the syringe containing Liquamycin LA-200 to the needle and slowly depress the plunger. If there is resistance to depression of the plunger, this indicates that the needle has slipped out of the vein (or is clogged) and the procedure will have to be repeated. Watch for any swelling under the skin near the needle, which would indicate that the medication is not going into the vein. Should this occur, it is best to try the vein on the opposite side of the neck.
5. Removing the needle. When injection is complete, remove needle with straight pull. Then apply pressure over area of injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

Restricted Drug (California)—
Use Only as Directed

Not For Human Use

NADA #113-232, Approved by FDA

TAKE TIME  OBSERVE LABEL DIRECTIONS

Distributed by:

Pfizer **Animal Health**
Exton, PA 19341, USA
Div. of Pfizer Inc

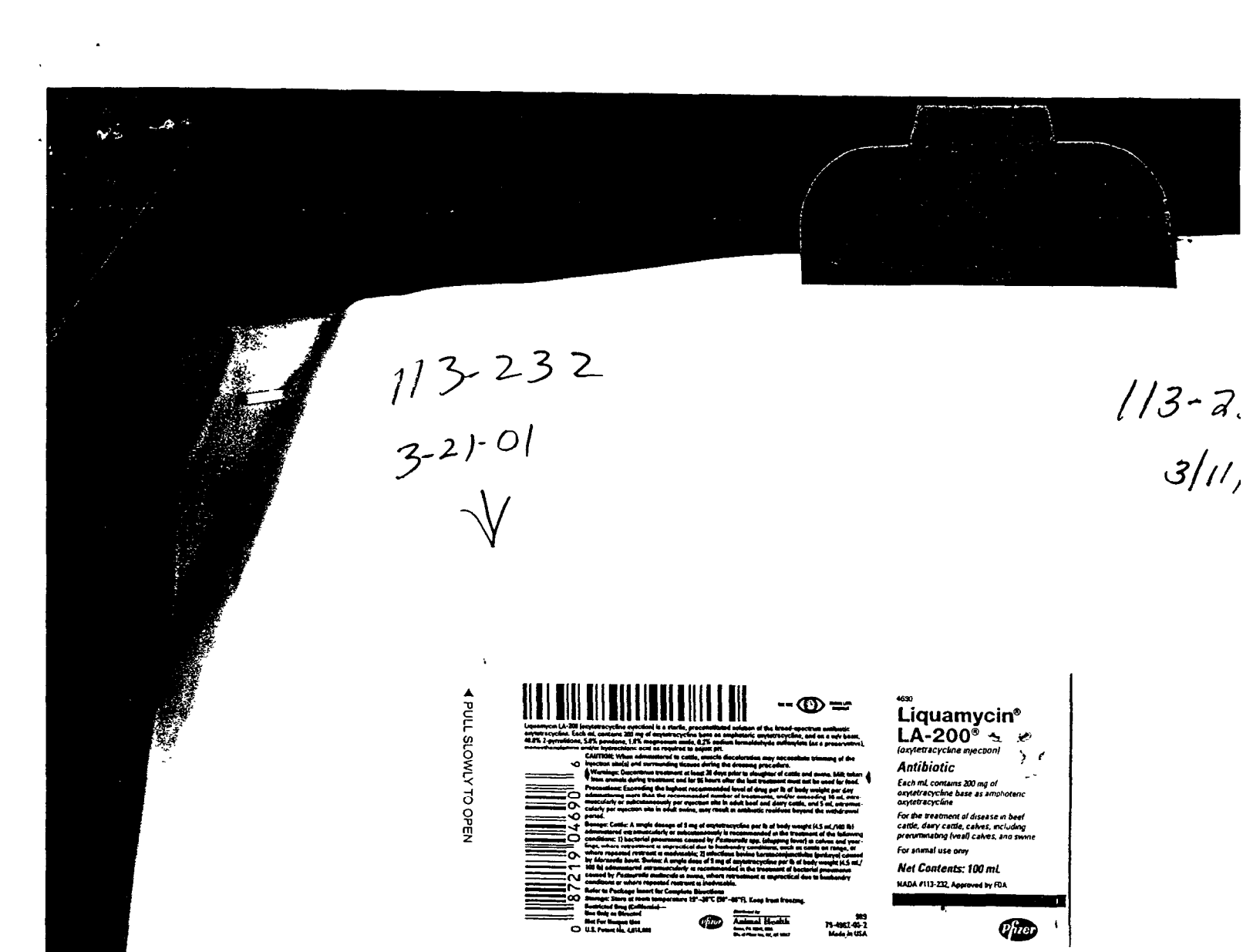
79-4984-00-1
June 1998

113-232

3-21-01

113-2

3/11,



▲ PULL SLOWLY TO OPEN

Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and as a vehicle, 40.8% 2-pyrrolidone, 5.0% povidone, 1.0% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

CAUTION: When administered to cattle, smooth discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

Warnings: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

Precautions: Exceeding the highest recommended level of drug per lb of body weight per day administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Dosage: Cattle: A single dosage of 5 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered via intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonias caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where restraint is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*. Swine: A single dose of 5 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered intramuscularly is recommended in the treatment of bacterial pneumonias caused by *Pasteurella multocida* in swine, where restraint is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15°-30°C (59°-86°F). Keep from freezing.

Restricted Drug (California)

Use Only as Directed

Not For Human Use

U.S. Patent No. 4,874,888

0 87219 04690 6

Distributed by Pfizer Animal Health

NADA #113-232, Approved by FDA

SRS

75-4867-05-2

Made in USA

4630

Liquamycin® LA-200®

(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline

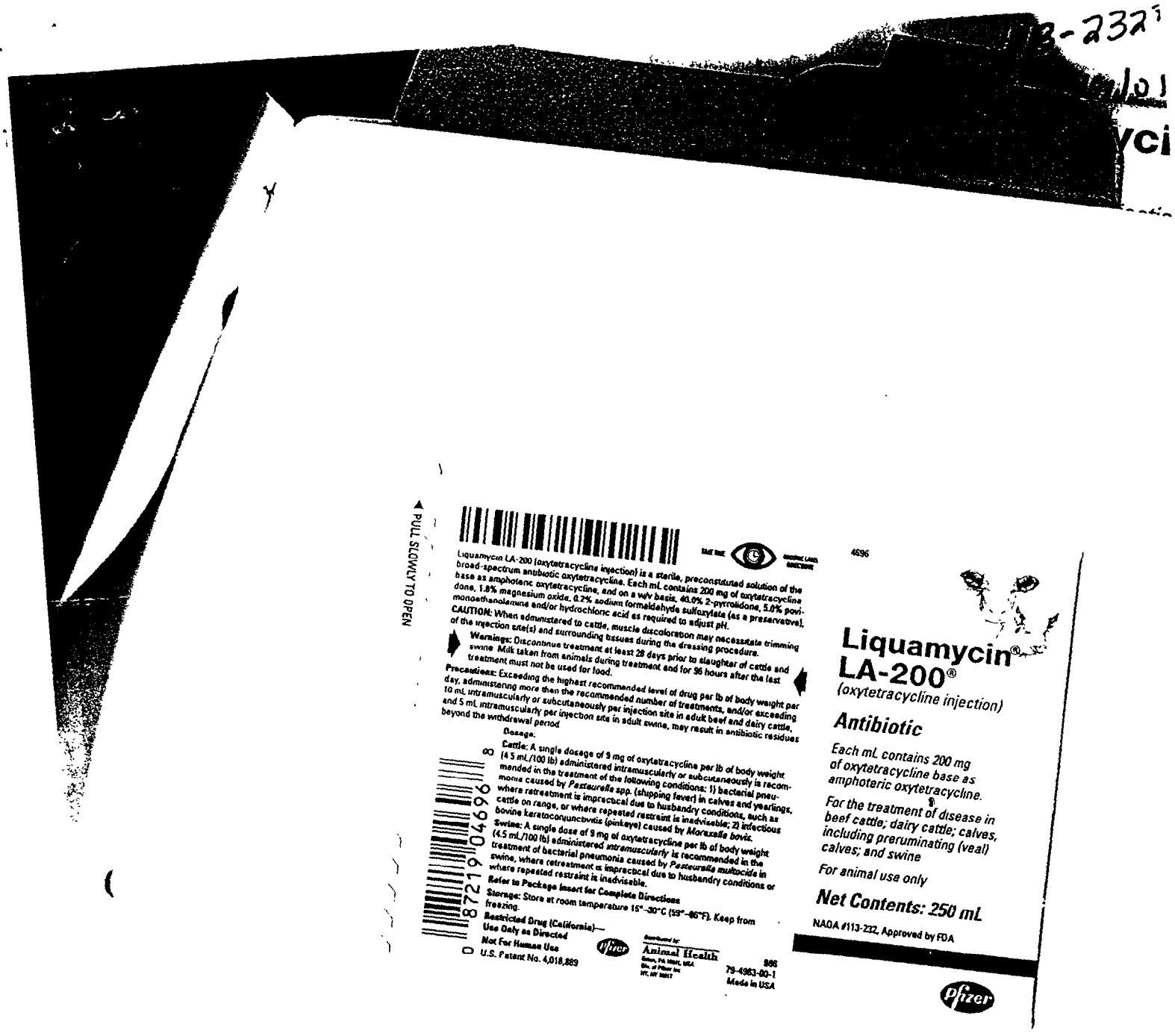
For the treatment of disease in beef cattle, dairy cattle, calves, including preruminating (veal) calves, and swine

For animal use only

Net Contents: 100 mL

NADA #113-232, Approved by FDA

Pfizer



PULL SLOWLY TO OPEN

Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and on a w/v basis, 40.0% 2-pyrrolidone, 5.0% povidone, 1.8% magnesium oxide, 0.7% sodium formaldehyde sulfoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

Warnings: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

Precautions: Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Dosage:

Cattle: A single dosage of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

Swine: A single dose of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

Restricted Drug (California)—
Use Only as Directed

Not For Human Use

U.S. Patent No. 4,018,889

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

988
79-4963-00-1
Made in USA

4696

Liquamycin® LA-200®

(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

Net Contents: 250 mL

NADA #113-232, Approved by FDA

Pfizer

▲ PULL SLOWLY TO OPEN

Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and on a w/v basis, 40.0% 2-pyrrolidone, 5.0% povidone, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

Warnings: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food

Precautions: Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Dosage:

Cattle: A single dosage of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

Swine: A single dose of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

Restricted Drug (California)—
Use Only as Directed
Not For Human Use
U.S. Patent No. 4,018,889

Distributed by:
Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

395
79-4984-00-1
Made in USA

4697

Liquamycin® LA-200®

(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

Net Contents: 500 mL

NADA #113-232, Approved by FDA

Oxytetracycline Injection (200 mg/mL) (oxytetracycline injection) is a sterile preconstituted solution of the broad spectrum antibiotic base oxytetracycline. Each mL contains 200 mg of oxytetracycline base as oxytetracycline amphoteric and on a w/v basis: 40.0% 2-pyrrolidone, 5.0% povidone, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulphoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

WARNING
Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

PRECAUTIONS
Exceeding the highest recommended level of drug per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Made in UK

Batch No

Exp

Oxytetracycline Injection

(200 mg/mL)

(OXYTETRACYCLINE INJECTION)
ANADA 200-306, APPROVED BY FDA

ANTIBIOTIC

Each mL contains 200 mg of oxytetracycline base as ampholeric oxytetracycline
For the treatment of disease in beef cattle, dairy cattle, calves, including preruminating (veal) calves; and swine

Net Contents: 100mL

Norbrook

DOSAGE
Oxytetracycline Injection (200 mg/mL)

CATTLE
A single dosage of 9 milligrams of oxytetracycline per pound of body weight (4.5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions:
(1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions such as cattle on range or where repeated restraint is inadvisable.
(2) infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

SWINE
A single dose of 9 milligrams of oxytetracycline per pound of body weight (4.5 mL/100 lb) administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Refer to package insert for complete indications, dosage and usage.
Store at room temperature 15 - 30 C (59 - 86 F).
Keep from freezing.
Distributed by

001156L01

Oxytetracycline Injection (200 mg/mL) (oxytetracycline injection) is a sterile preconstituted solution of the broad spectrum antibiotic base oxytetracycline Each mL contains 200 mg of oxytetracycline base as oxytetracycline amphoteric and on a w/v basis, 40 0% 2-pyrrolidone 5 0% povidone 1 8% magnesium oxide 0 2% sodium formaldehyde sulphoxylate (as a preservative) monoethanolamine and/or hydrochloric acid as required to adjust pH

WARNING
Discontinue treatment at least 28 days prior to slaughter of cattle and swine Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food

PRECAUTIONS
Exceeding the highest recommended level of drug per pound of body weight per day administering more than the recommended number of treatments and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramscularly per injection site in adult swine may result in antibiotic residues beyond the withdrawal period

Made in UK.

Batch No.

Exp

Oxytetracycline Injection

(200 mg/mL)

(OXYTETRACYCLINE INJECTION)
ANADA 200-306, APPROVED BY FDA

ANTIBIOTIC

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline
For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veall calves; and swine

Net Contents: 250mL

Norbrook

DOSAGE
Oxytetracycline Injection (200 mg/mL)

CATTLE
A single dosage of 9 milligrams of oxytetracycline per pound of body weight (4 5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions

(1) bacterial pneumonia caused by *Pasteurella* spp (shipping fever) in calves and yearlings where retreatment is impractical due to husbandry conditions such as cattle on range, or where repeated restraint is inadvisable
(2) infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*

SWINE
A single dose of 9 milligrams of oxytetracycline per pound of body weight (4 5 mL/100 lb) administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable

Refer to package insert for complete indications dosage and usage
Store at room temperature 15 - 30 C (59 - 86 F)
Keep from freezing
Distributed by

002156L01

Oxytetracycline Injection (200 mg/mL) (oxytetracycline injection) is a sterile preconstituted solution of the broad spectrum antibiotic base oxytetracycline. Each mL contains 200 mg of oxytetracycline base as oxytetracycline amphoteric and on a w/v basis: 40.0% 2-pyrrolidone, 5.0% povidone, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulphoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

WARNING.
Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

PRECAUTIONS:
Exceeding the highest recommended level of drug per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Made in UK.

Batch No.

Exp:

0 00090 0000

Oxytetracycline Injection

(200 mg/mL)

(OXYTETRACYCLINE INJECTION)
ANADA 200-306, APPROVED BY FDA

ANTIBIOTIC

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.
For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine.

Net Contents: 500mL

Norbrook®

DOSAGE
Oxytetracycline Injection (200 mg/mL)

CATTLE
A single dosage of 9 milligrams of oxytetracycline per pound of body weight (4.5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions:

(1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings where retreatment is impractical due to husbandry conditions such as cattle on range or where repeated restraint is inadvisable.
(2) infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

SWINE
A single dose of 9 milligrams of oxytetracycline per pound of body weight (4.5 mL/100 lb) administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Refer to package insert for complete indications, dosage and usage.
Store at room temperature 15 - 30 C (59 - 86 F).
Keep from freezing.
Distributed by:

003156L01

USA

...ne injection (200 mg/mL) is a sterile ... solution of the broad spectrum ... oxytetracycline

...AUTION
...e administered to cattle muscle ... may necessitate trimming of the ... site(s) and surrounding tissues during ... processing procedure

WARNING
... treatment at least 28 days prior to ... cattle and swine. Milk taken from ... during treatment and for 96 hours after the ... animals must not be used for food

...DVERSE REACTIONS
... higher than recommended level of drug per ... weight, per day, administering more than the ... recommended number of treatments, and/or exceeding ... volume per injection site or subcutaneously per injection ... site. Beef cattle and dairy cattle and 5 mL ... per injection site in adult swine may ... tissue residues beyond the withdrawal period

... Package Insert for Complete Directions

...Storage
... room temperature (15° 30°C 59° 86°F) ... excursions permitted

...Restricted Drug(s): California

...Not for Human Use

...Use as Directed

Manufactured for

Made in the U.K.

Oxytetracycline Injection (200 mg/mL)
(oxytetracycline injection)
ANADA 200-306, approved by FDA

ANTIBIOTIC

Each mL contains 200 mg of oxytetracycline base as ampholeric oxytetracycline
For the treatment of disease in beef cattle, dairy cattle, calves, including preruminating (veal) calves, and swine

For animal use only

Net Contents 500 mL

Oxytetracycline Injection (200 mg/mL)

(Oxytetracycline Injection) ANADA 200-306, approved by FDA

500 mL

Norbrook

CATTLE DOSAGE GUIDE
At the first signs of pneumonia or pinkeye,* administer a single dose of Oxytetracycline Injection (200 mg/mL) by deep intramuscular injection, or subcutaneously, according to the following weight categories **

Animal Weight (lb)	Number of mL or cc
100	4.5
200	9.0
300	13.5
400	18.0
500	22.5
600	27.0
700	31.5
800	36.0
900	40.5
1000	45.0
1100	49.5
1200	54.0

* See package insert for dosing instructions for other indicated diseases and full product information
** Do not administer more than 10 mL at any one injection site (1-2 mL per site in small calves)
Discontinue treatment at least 28 days prior to slaughter

SWINE DOSAGE GUIDE
At the first signs of pneumonia, * administer Oxytetracycline Injection (200 mg/mL) by deep intramuscular injection, according to the following weight categories **

Animal Weight (lb)	Number of mL or cc
10	0.5
25	1.1
50	2.3
75	3.4
100	4.5
125	5.6
150	6.8
175	7.9
200	9.0
225	10.1
250	11.3
275	12.4
300	13.5
325	14.6

* See package insert for dosing instructions for other indicated diseases and full product information
** Do not administer more than 5 mL at any one injection site
Discontinue treatment at least 28 days prior to slaughter

PMS 3725 C
PMS BLACK C
204057C01

[illegible] 200 mg/mL is a sterile [illegible] solution of the broad spectrum [illegible]

[illegible] administered to cattle muscle discoloration [illegible] trimming of the injection site(s) [illegible] tissues during the dressing

WARNING [illegible] at least 28 days prior to slaughter [illegible] Milk taken from animals during [illegible] hours after the last treatment must [illegible]

[illegible] recommended level of drug per lb of [illegible] administering more than the [illegible] treatments and/or exceeding 10 [illegible] subcutaneously per injection site in [illegible] and 5 mL intramuscularly [illegible] swine may result in antibiotic [illegible] withdrawal period

[illegible] insert for Complete Directions

[illegible] temperature [illegible] 20°C (59°-86°F)

Oxytetracycline Injection (200 mg/mL)
(oxytetracycline injection)
ANADA 200-306, approved by FDA

ANTIBIOTIC

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline

For the treatment of disease in beef cattle, dairy cattle, calves, including preruminating (veal) calves, and swine

For animal use only

Net Contents 250 mL

Oxytetracycline Injection
(200 mg/mL)

(Oxytetracycline Injection)
ANADA 200-306,
approved by FDA

250 mL

Norbrook

B N

DOM

EXP

USA

CATTLE DOSAGE GUIDE

At the first signs of pneumonia or pinkeye,* administer a single dose of Oxytetracycline Injection (200 mg/mL) by deep intramuscular injection, or subcutaneously, according to the following weight categories **

Animal Weight (lb)	Number of mL or cc
100	4.5
200	9.0
300	13.5
400	18.0
500	22.5
600	27.0
700	31.5
800	36.0
900	40.5
1000	45.0
1100	49.5
1200	54.0

* See package insert for dosing instructions for other indicated diseases and full product information
** Do not administer more than 10 mL at any one injection site (1-2 mL per site in small calves)
Discontinue treatment at least 28 days prior to slaughter

SWINE DOSAGE GUIDE

At the first signs of pneumonia, * administer Oxytetracycline Injection (200 mg/mL) by deep intramuscular injection, according to the following weight categories **

Animal Weight (lb)	Number of mL or cc
10	0.5
25	1.1
50	2.3
75	3.4
100	4.5
125	5.6
150	6.8
175	7.9
200	9.0
225	10.1
250	11.3
275	12.4
300	13.5
325	14.6

* See package insert for dosing instructions for other indicated diseases and full product information
** Do not administer more than 5 mL at any one injection site
Discontinue treatment at least 28 days prior to slaughter

PMS [illegible]
PMS BLACK C
204056C01

Batch No

Exp

USA

Oxytetracycline Injection (200 mg/mL) is a sterile preconstituted solution of the broad-spectrum antibiotic oxytetracycline

CAUTION
When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure

WARNING
Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food

PRECAUTIONS
Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef cattle and dairy cattle, and 5 mL intramuscularly per injection site in adult swine may result in antibiotic residues beyond the withdrawal period
Refer to Package Insert for Complete Directions
Storage: Store at room temperature 15° - 30°C (59° - 86°F). Keep from freezing

Restricted Drug(s) (California)

Not for Human Use

Use Only as Directed

Manufactured for

Made in the U.K.

Oxytetracycline Injection (200 mg/mL)
(oxytetracycline injection)
ANADA 200-306, approved by FDA

ANTIBIOTIC

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline
For the treatment of disease in beef cattle, dairy cattle, calves, including preruminating (veall calves), and swine

For animal use only

Net Contents: 100 mL

Oxytetracycline Injection (200 mg/mL)

(Oxytetracycline Injection)
ANADA 200-306, approved by FDA

100 mL

Norbrook

BN

DOM

EXP

CATTLE DOSAGE GUIDE
At the first signs of pneumonia or pinkeye,* administer a single dose of Oxytetracycline Injection (200 mg/mL) by deep intramuscular injection or subcutaneously according to the following weight categories:**

Animal Weight (lb)	Number of mL or cc
100	4.5
200	9.0
300	13.5
400	18.0
500	22.5
600	27.0
700	31.5
800	36.0
900	40.5
1000	45.0
1100	49.5
1200	54.0

* See package insert for dosing instructions for other indicated diseases and full product information
** Do not administer more than 10 mL at any one injection site (1-2 mL per site in small calves)
Discontinue treatment at least 28 days prior to slaughter

SWINE DOSAGE GUIDE
At the first signs of pneumonia,* administer Oxytetracycline Injection (200 mg/mL) by deep intramuscular injection according to the following weight categories:**

Animal Weight (lb)	Number of mL or cc
10	0.5
25	1.1
50	2.3
75	3.4
100	4.5
125	5.6
150	6.8
175	7.9
200	9.0
225	10.1
250	11.3
275	12.4
300	13.5
325	14.6

* See package insert for dosing instructions for other indicated diseases and full product information
** Do not administer more than 5 mL at any one injection site
Discontinue treatment at least 28 days prior to slaughter

PMS 072 C

PMS BLACK C

204055C01

OXYTETRACYCLINE INJECTION

OXYTETRACYCLINE INJECTION (200 mg/mL)
(oxytetracycline injection)
ANADA 200-306, approved by FDA

ANTIBIOTIC

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For use in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine.

For animal use only.

Read Entire Package Insert Carefully Before Using This Product.

Oxytetracycline Injection (200 mg/mL) (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline by injection.

Oxytetracycline Injection (200 mg/mL) does not require refrigeration; however, it is recommended that it be stored at room temperature,15°-30°C (59°-86°F). The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum, or exudates.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

WARNING:
Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

PRECAUTIONS:
Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Reactions of an allergic or anaphylactic nature, sometimes fatal, have been known to occur in hypersensitive animals following the injection of oxytetracycline. Such adverse reactions can be characterized by signs such as restlessness, erection of hair, muscle trembling; swelling of eyelids, ears, muzzle, anus, and vulva (or scrotum and sheath in males); labored breathing, defecation and urination, glassy-eyed appearance, eruption of skin plaques, frothing from the mouth, and prostration. Pregnant animals that recover may subsequently abort. At the first sign of any adverse reaction, discontinue use of this product and administer epinephrine at the recommended dosage levels. Call a veterinarian immediately.

Shock may be observed following intravenous administration, especially where highly concentrated materials are involved. To minimize this occurrence, it is recommended that Oxytetracycline Injection (200 mg/mL) be administered *slowly* by this route.

Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animals, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving Oxytetracycline Injection (200 mg/mL) in conjunction with penicillin.

STORAGE: Store at room temperature 15°-30°C (59°-86°F). Keep from freezing.

CARE OF SICK ANIMALS: The use of antibiotics in the management of diseases is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with Oxytetracycline Injection (200 mg/mL) show a noticeable improvement within 24-48 hours. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, costs and needless losses. Good housing, sanitation, and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased animals.

INDICATIONS:
Oxytetracycline Injection (200 mg/mL) is intended for use in treatment of the following diseases in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine when due to oxytetracycline-susceptible organisms:

Cattle: Oxytetracycline Injection (200 mg/mL) is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., and *Hamophilus* spp., infectious bovine keratoconjuctivitis (pink eye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*: and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

Swine: Oxytetracycline Injection (200 mg/mL) is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*.

In sows, Oxytetracycline Injection (200 mg/mL) is indicated as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

DOSAGE:
Cattle: Oxytetracycline Injection (200 mg/mL) is to be administered by intramuscular, subcutaneous, or intravenous injection to beef cattle; dairy cattle; and calves, including preruminating (veal) calves.

A single dosage of 9 mg of Oxytetracycline Injection (200 mg/mL) per lb of body weight administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions:

(1) bacterial pneumonia caused by *Pasteurella* spp., (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable.

(2) Infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

Oxytetracycline Injection (200 mg/mL) can also be administered by intravenous, subcutaneous, or intramuscular injection at a level of 3-5 mg of oxytetracycline per lb of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg/lb of body weight per day is recommended. Treatment should be continued 24-48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24-48 hours of the beginning of treatment.

Swine: In swine a single dosage of 9 mg of Oxytetracycline Injection (200 mg/mL) per lb of body weight administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Oxytetracycline Injection (200 mg/mL) can also be administered by intramuscular injection at a level of 3-5 mg of oxytetracycline per lb of body weight per day. Treatment should be continued 24-48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24-48 hours of the beginning of treatment.

For sows, administer once intramuscularly 3 mg of oxytetracycline per lb of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb of body weight and under, Oxytetracycline Injection (200 mg/mL) should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

	9 mg/lb Dosage Volume of Undiluted Oxytetracycline Injection (200 mg/mL)	3 or 5 mg/lb Dosage Volume of Diluted Oxytetracycline Injection (200 mg/mL)		
Body weight	**9 mg/lb**	**3 mg/lb**	**Dilution***	**5 mg/lb**
5 lb	0.2 mL	0.6 mL	1:7	1.0 mL
10 lb	0.5 mL	0.9 mL	1:5	1.5 mL
25 lb	1.1 mL	1.5 mL	1:3	2.5 mL

* To prepare dilutions, add one part of Oxytetracycline Injection (200 mg/mL) to 3, 5 or 7 parts of sterile water, or 5% dextrose solution as indicated; the diluted product should be used immediately.

DIRECTIONS FOR USE:
Oxytetracycline Injection (200 mg/mL) is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, Oxytetracycline Injection (200 mg/mL) should be warmed to room temperature before administration to animals. Before withdrawing the solution from the bottle, disinfect the rubber cap on the bottle with suitable disinfectant, such as 70% alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 16-18 gauge and 1-1½ inches long are adequate for intramuscular and subcutaneous injections. Needles of 2-3 inches in length are recommended for intravenous use.

Intramuscular Administration:
Intramuscular injections should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle such as in the rump, hip, or thigh regions; avoid blood vessels and major nerves. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. No more than 10 mL should be injected intramuscularly at any one site in adult beef and dairy cattle, and not more than 5 mL per site in adult swine; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1-2 mL per site is injected in small calves.

Subcutaneous Administration:
Subcutaneous injections in beef cattle, dairy cattle, and calves, including preruminating (veal) calves, should be made by directing the needle of suitable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the tip of the needle has penetrated the skin but is not lodged in muscle. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. The solution should be injected slowly into the area between the skin and muscles. No more than 10 mL should be injected subcutaneously at any one site in adult beef and dairy cattle; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1-2 mL per site is injected in small calves.

Intravenous Administration:
Oxytetracycline Injection (200 mg/mL) may be administered intravenously to beef and dairy cattle. As with all highly concentrated materials, Oxytetracycline Injection (200 mg/mL) should be administered *slowly* by the intravenous route.

Preparation of the Animal for Injection:

1. Approximate the location of vein. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the brisket and slightly above and to the side of the windpipe (see Fig I).

2. Restraint. A stanchion or chute is ideal for restraining the animal. With a halter, rope, or cattle leader (nose tongs), pull the animal's head around the side of the stanchion, cattle chute, or post in such a manner to form a bow in the neck (see Fig. II), then snub the head securely to prevent movement. By forming the bow in the neck, the outside curvature of the bow tends to expose the jugular vein and make it easily accessible.
Caution: Avoid restraining the animal with a tight rope or halter around the throat or upper neck which might impede blood flow. Animals that are down present no problem so far as restraint is concerned.

3. Clip hair in area where injection is to be made (over the vein in the upper third of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.

Figure I

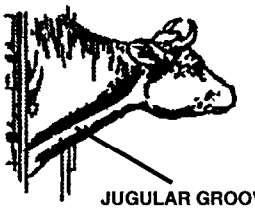
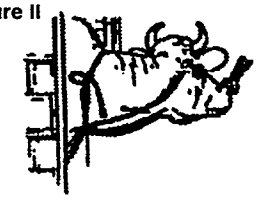


Figure II



Entering the Vein and Making the Injection:

1. Raise the vein. This is accomplished by tying the choke rope tightly around the neck close to the shoulder. The rope should be tied in such a way that it will not come loose and so that it can be untied quickly by pulling the loose end (see Fig. II). In thick-necked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back to the heart. Under ordinary conditions it cannot be seen or felt with the fingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands out and can be easily seen and felt in thin-necked animals. As a further check in identifying the vein, tap it with the fingers in front of the choke rope. Pulsations that can be seen or felt with the fingers in front of the point being tapped will confirm the fact that the vein is properly distended. It is impossible to put the needle into the vein unless it is distended. Experienced operators are able to raise the vein simply by hand pressure, but the use of a choke rope is more certain.

2. Inserting the needle. This involves three distinct steps. First, insert the needle through the hide. Second, insert the needle into the vein. This may require two or three attempts before the vein is entered. The vein has a tendency to roll away from the point of the needle, especially if the needle is not sharp. The vein can be steadied with the thumb and finger of one hand. With the other hand, the needle point is placed directly over the vein, slanting it so that its direction is along the length of the vein, either toward the head or toward the heart. Properly positioned this way, a quick thrust of the needle will be followed by a spurt of blood through the needle, which indicates that the vein has been entered. Third, once in the vein, the needle should be inserted along the length of the vein all the way to the hub, exercising caution to see that the needle does not penetrate the opposite side of the vein. Continuous steady flow of blood through the needle indicates that the needle is still in the vein. If blood does not flow continuously, the needle is out of the vein (or clogged) and another attempt must be made. If difficulty is encountered, it may be advisable to use the vein on the other side of the neck.

3. While the needle is being placed in proper position in the vein, an assistant should get the medication ready so that the injection can be started without delay after the vein has been entered.

4. Making the injection. With the needle in position as indicated by continuous flow of blood, release the choke rope by a quick pull on the free end. This is essential - the medication cannot flow into the vein while it is blocked. Immediately connect the syringe containing Oxytetracycline Injection (200 mg/mL) (oxytetracycline injection) to the needle and slowly depress the plunger. If there is resistance to depression of the plunger, this indicates that the needle has slipped out of the vein (or is clogged) and the procedure will have be to repeated. Watch for any swelling under the skin near the needle, which would indicate that the medication is not going into the vein. Should this occur, it is best to try the vein on the opposite side of the neck.

5. Removing the needle. When injection is complete, remove needle with straight pull. Then apply pressure over area of injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

Not for Human Use. Restricted Drug. Use Only as Directed.

MANUFACTURED FOR:

MADE IN THE UK

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